Re-evaluation Decision RVD2010-11

3-Trimethoxysilyl Propyldimethyl Octadecyl Ammonium Chloride

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Re-evaluation Decision

After a re-evaluation of the antimicrobial 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride for sale and use in Canada.

An evaluation of available scientific information found that products containing 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride uses, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride was first presented in Proposed Re-evaluation Decision document PRVD2010-09, *3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride*, a consultation document[1]. This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2010-09. To comply with this decision, registrants of products containing 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

The antimicrobial 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

The USEPA re-evaluated 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride and published its conclusions in a 2007 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2010-09, *3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride*.

What Is 3-(Trimethoxysilyl) Propyldimethyl Octadecyl Ammonium Chloride?

3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride is an antimicrobial used as a material preservative. It is used in or on textiles, towlettes, tissue wipes, fibers, roofing materials, filters, filter materials, foam, fibreglass, plastic products, rubber products, fan/humidifier belts, and hard indoor surfaces. This chemical is handled by professional workers and is added during the manufacturing process of treated articles. In addition, this active ingredient may be applied in buildings to control microbial growth on surfaces.

Health Considerations

Can Approved Uses of 3-(Trimethoxysilyl) Propyldimethyl Octadecyl Ammonium Chloride Affect Human Health?

3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride is unlikely to affect your health when used according to the revised label directions.

People could be exposed to 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride was unlikely to affect human health provided that risk-reduction measures were implemented.

These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required by the PMRA.

Environmental Considerations

What Happens When 3-(Trimethoxysilyl) Propyldimethyl Octadecyl Ammonium Chloride Is Introduced Into the Environment?

3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride is unlikely to affect non-target organisms when used according to the revised label directions.

The USEPA concluded that indoor uses of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride would result in minimal environmental exposure, and were unlikely to affect non-target organisms. These conclusions apply to the Canadian situation.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional personal protective equipment to protect workers
- Limit use of this active ingredient to materials and products that do not come into direct contact with food or feed
- Additional warning signals, advisory and basic hygiene statements on end-use product labels

Environment

- Update label statements to further protect the environment from effluent discharge

Other Information

Any person may file a notice of objection[3] regarding this decision on 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.